IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
CLARKSBURG DIVISION

REGENERON PHARMACEUTICALS, INC., Plaintiff, v. MYLAN PHARMACEUTICALS INC., Defendant.	Case No. 1:22-cv-00061-TSK **JURY TRIAL DEMANDED**

MEMORANDUM IN SUPPORT OF PLAINTIFF'S MOTION FOR JUDGMENT ON THE PLEADINGS AS TO DEFENDANT'S INEQUITABLE CONDUCT DEFENSES AND COUNTERCLAIMS

Defendant Mylan Pharmaceuticals Inc. ("Mylan") asserts in its affirmative defenses and counterclaims, without adequate factual allegations, that Plaintiff Regeneron Pharmaceuticals, Inc. ("Regeneron") engaged in inequitable conduct. Because Mylan does not allege facts sufficient to state defenses or counterclaims based on inequitable conduct, the Court should enter judgment on the pleadings for Regeneron under Federal Rule of Civil Procedure 12(c), sparing the parties and the Court needless discovery and attendant disputes, and narrowing the issues for trial. Regeneron asked Mylan to withdraw its deficient pleadings, but Mylan refused, necessitating this Motion.

INTRODUCTION

Regeneron brought this case to stop Mylan from infringing patents protecting Regeneron's groundbreaking ophthalmology medicine EYLEA® (aflibercept), a drug used to treat wet age-related macular degeneration and other serious eye conditions that can ultimately lead to blindness. In response, Mylan claims inequitable conduct. Courts carefully circumscribe

this defense to avoid the distractions it can introduce to litigation, and Mylan's deficient pleadings illustrate why.

Mylan's Answer asserts inequitable conduct in support of two affirmative defenses and counterclaims as to six patents: U.S. Patent Nos. 9,254,338; 9,669,069; 10,130,681; 10,857,205; 10,888,601; and 11,253,572.[1] *See* ECF 47 at 74, 75, 88-90, 92-94, 96-98, 104, 105, 116. By stipulation, only two of those patents—the '601 and '572 patents—are at issue at this stage of the litigation. *See* ECF 88 at 1. This Motion therefore seeks judgment only on Mylan's defenses and counterclaims as to the '601 and '572 patents.[2]

Mylan does not allege that inequitable conduct occurred during the prosecution of the '601 patent or the '572 patent, both of which concern how much and how often aflibercept should be administered, permitting more time between doses than patients enjoyed with previous treatments while achieving therapeutic gains. Instead, Mylan argues without sufficient factual basis that three instances of alleged inequitable conduct during proceedings concerning two earlier patents in the same family (the '338 and '069 patents) tainted the '601 and '572 patents, rendering them unenforceable. This argument fails for multiple reasons, each of which constitutes a sufficient basis to dismiss Mylan's claims.

First, and as a threshold matter, Mylan does not allege with particularity that inequitable conduct occurred in the prosecution of, or other proceedings concerning, the '338 and '069 patents. For example, it does not identify an individual who made a misrepresentation or

[1] These patents are referred to as the "'338 patent," "'069 patent," "'681 patent," "'205 patent," "'601 patent," and "'572 patent," respectively.

[2] Mylan's allegations as to the other four patents fail for similar reasons, and Regeneron will be entitled to judgment on the pleadings when those patents are litigated. But the Court need not address them now.

omission with scienter, as required by governing Federal Circuit law. Having failed to allege inequitable conduct regarding the original patents, Mylan cannot claim that any such conduct taints the later patents.

Second, one of Mylan's three theories asserts the non-disclosure of various materials to the Patent and Trademark Office ("PTO") in the applications for the '338 and '069 patents. But Regeneron disclosed those materials to the PTO when applying for the '601 and '572 patents, so any earlier non-disclosure was cured as to those later patents.

Third, Mylan's other theories assert that Regeneron made misrepresentations to the PTO, but the only purported misrepresentations Mylan cites were not material assertions of fact but mere attorney argument, which cannot form the basis of an inequitable conduct claim or defense.

For all these reasons, the Court should grant Regeneron's Motion for Judgment on the Pleadings as to Mylan's inequitable conduct defenses (Nos. 60-61) and counterclaims (Counts 12 and 21) as to the '601 and '572 patents.[3]

LEGAL STANDARD

A. Motion for Judgment on the Pleadings

Under Rule 12(c), "[a]fter the pleadings are closed—but early enough not to delay trial—a party may move for judgment on the pleadings." Fed. R. Civ. P. 12(c). A court may grant judgment on the pleadings against both affirmative defenses and counterclaims. *See Acantha LLC v. DePuy Orthopaedics Inc*, 2017 WL 5186376, at *2 (E.D. Wis. Nov. 8, 2017) (granting patentee's motion for judgment on the pleadings against infringer's inequitable conduct

[3] Affirmative defense No. 60, "unclean hands," invokes only inequitable conduct, which is also asserted in affirmative defense No. 61. *See Consol. Aluminum Corp. v. Foseco Int'l Ltd.*, 910 F.2d 804, 812 (Fed. Cir. 1990) ("[W]hat we have termed 'inequitable conduct' is no more than the unclean hands doctrine applied to particular conduct before the PTO.").

affirmative defense and counterclaim); *Smithfield Foods, Inc. v. United Food & Com. Workers Int'l Union*, 593 F. Supp. 2d 840, 842 (E.D. Va. 2008) (granting plaintiff judgment on the pleadings on defendant's affirmative defenses). The Court must grant judgment as to any defense or counterclaim that is insufficiently alleged, even if it finds others adequately stated. *See, e.g.*, *Indep. News, Inc. v. City of Charlotte*, 568 F.3d 148, 157 (4th Cir. 2009) (affirming grant of partial judgment on the pleadings); *Figlioli v. Liberty Life Assurance Co. of Bos.*, 2018 WL 834616, at *4 (N.D.W. Va. Feb. 12, 2018) (granting partial judgment on the pleadings).[4]

A Rule 12(c) motion is reviewed under the same standards as a Rule 12(b)(6) motion for failure to state a claim. *Edwards v. City of Goldsboro,* 178 F.3d 231, 243 (4th Cir. 1999); *U.S. Northstar Founds., Inc. v. Satterfield & Pontikes Constr., Inc.*, 2013 WL 12137650, at *3 (N.D.W. Va. June 19, 2013). In evaluating both, a court must accept the nonmoving party's factual allegations as true and assess whether its allegations "contain 'enough facts to state a claim to relief that is plausible on its face.'" *Figlioli*, 2018 WL 834616, at *2 (citation omitted). A claim is plausible only when a party "pleads factual content that allows the court to draw the reasonable inference that the [opposing party] is liable for the misconduct alleged." *Id.* (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). "Legal conclusions, recitations of the elements of a cause of action, and bare assertions devoid of further factual enhancement" will not suffice. *Miller v. Liberty Mut. Ins. Co.*, 2013 WL 12137238, at *2 (N.D.W. Va. Nov. 4, 2013), *on reconsideration in part*, 2013 WL 12137267 (N.D.W. Va. Dec. 3, 2013).

[4] Federal Circuit law governs substantive patent law in this case, but Fourth Circuit law governs procedural issues not unique to the Federal Circuit's exclusive jurisdiction. *See Arendi S.A.R.L. v. LG Elecs. Inc.*, 47 F.4th 1380, 1384 (Fed. Cir. 2022).

B. Inequitable Conduct

The judicially created doctrine of inequitable conduct renders a patent unenforceable when an alleged infringer demonstrates that the patent holder engaged in "egregious affirmative acts of misconduct" intended to deceive the PTO or failed to disclose material information to the PTO in seeking the patent. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1287 (Fed. Cir. 2011). Because a finding of inequitable conduct renders a patent unenforceable and can "spawn antitrust and unfair competition claims," *id.* at 1289, it is one of the most serious allegations a would-be infringer can make—not "a magic incantation to be asserted against every patentee," *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1331 (Fed. Cir. 2009) (citation omitted). An accusation of inequitable conduct "cast[s] a dark cloud over the patent's validity and paint[s] the patentee as a bad actor." *Therasense*, 649 F.3d at 1288. An unjustified accusation (at best) needlessly expands discovery, causing delay, and (at worst) "may deprive patentees of their earned property rights." *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1182 (Fed. Cir. 1995). For these reasons, the Federal Circuit has called inequitable conduct "the 'atomic bomb' of patent law," *Therasense*, 649 F.3d at 1288 (citation omitted), a weapon not to be used lightly.

To guard against unfounded allegations "plagu[ing]" the courts and the "entire patent system," *id.* at 1289, a party alleging inequitable conduct as either a defense or a counterclaim must plead the circumstances of the conduct with particularity, *Central Admixture Pharmacy Services, Inc. v. Advanced Cardiac Solutions, P.C.*, 482 F.3d 1347, 1356-57 (Fed. Cir. 2007). The Federal Circuit "appl[ies] [its] own law, not the law of the regional circuit, to the question of whether inequitable conduct has been pleaded with particularity under Rule 9(b)." *Exergen*, 575 F.3d at 1326. This requirement demands that the pleading party "identif[y] . . . the specific who, what, when, where, and how of the material misrepresentation or omission committed before the

PTO." *Id.* at 1327. It also requires that the pleading "include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO." *Id.* at 1328-29; *see Therasense*, 649 F.3d at 1290 (explaining that inequitable conduct requires a party to have acted "knowingly and deliberately with the purpose of defrauding the PTO and the courts").

The Federal Circuit instructs courts to be vigilant in policing the sufficiency of inequitable conduct allegations, including by examining whether each element has been pleaded with the requisite particularity. *Therasense*, 649 F.3d at 1290; *Pfizer Inc. v. Teva Pharms. USA, Inc.*, 803 F. Supp. 2d 409, 432 (E.D. Va.), *amended*, 803 F. Supp. 2d 464 (E.D. Va. 2011) ("[C]ourts must take an active role in examining the propriety of inequitable conduct claims . . . ."). When a party fails to plead each element with particularity, its claim must be dismissed. *See Exergen*, 575 F.3d at 1329-30; *Webasto Thermo & Comfort N. Am., Inc. v. Bestop, Inc.*, 326 F. Supp. 3d 521, 530 (E.D. Mich. 2018) (dismissing inequitable conduct counterclaim when defendant failed to plead all "necessary elements," including the "who" and "specific intent," with particularity); *Stowe Woodward, L.L.C. v. Sensor Prod., Inc.*, 230 F.R.D. 463, 467 (W.D. Va. 2005) (dismissing inequitable conduct counterclaim when defendant "pled several facets of the claim with sufficient particularity, [but did] not completely fulfill[] the requirements of heightened pleading").

C. Infectious Inequitable Conduct

Demonstrating that inequitable conduct during an earlier patent proceeding infects a patent issued in a subsequent proceeding is an "uphill battle." *Eon Corp. IP Holdings, LLC v. T-Mobile USA, Inc.*, 2011 WL 13134896, at *8 (E.D. Tex. Dec. 13, 2011), *report and recommendation adopted*, 2012 WL 12893881 (E.D. Tex. Jan. 18, 2012); *see Arthrocare*

Corp. v. Smith & Nephew, Inc., 310 F. Supp. 2d 638, 675 (D. Del. 2004), *aff'd in part, vacated in part, remanded*, 406 F.3d 1365 (Fed. Cir. 2005) ("Charges of infectious inequitable conduct are disfavored even more than charges of inequitable conduct." (citation omitted)). Inequitable conduct associated with one patent can render a later patent unenforceable only if the misconduct bears an "immediate and necessary relation" to the later patent's enforcement. *Gilead Scis., Inc. v. Merck & Co.*, 888 F.3d 1231, 1239 (Fed. Cir. 2018) (citation omitted); *see Guardant Health, Inc. v. Found. Med., Inc.*, 2020 WL 2477522, at *5 (D. Del. Jan. 7, 2020).

Any "relation" between earlier alleged non-disclosure and the enforcement of a later patent is severed when a patent owner discloses the relevant material when applying for the later patent. *See, e.g.*, *Bos. Sci. Corp. v. Cordis Corp.*, 2008 WL 11387094, at *6 (N.D. Cal. Mar. 21, 2008) (finding that, given disclosure of previously undisclosed references, defendant could not demonstrate "immediate and necessary relation" to earlier inequitable conduct). As the Federal Circuit has explained, "[t]he essence of the duty of disclosure is to get relevant information before an examiner in time for him to act on it." *Young v. Lumenis, Inc.*, 492 F.3d 1336, 1349 (Fed. Cir. 2007). That standard is satisfied when the examiner has all prior art necessary to evaluate the application at hand. *See id.* ("[W]e cannot agree that there was inequitable conduct resulting from the 'failure to disclose material information' when that information was disclosed to the PTO in time for the examiner to consider it."). The case Mylan cites in its counterclaims, *eSpeed, Inc. v. Brokertec USA, L.L.C.*, 417 F. Supp. 2d 580 (D. Del. 2006) (at ECF 47 at 94, 98), illustrates the point. Although the court held that failure to disclose prior art in one application infected a later one, the misconduct ran far deeper than a mere failure to disclose. Instead, "even when the applicants did disclose" the prior art in the later application, "they made material misrepresentations to the PTO about" it, compounding the misconduct. *See id*. at 597. In

contrast, when a patentee fairly discloses prior art in a later application, any non-disclosure in previous patent proceedings cannot infect the later patent. *See Bos. Sci.*, 2008 WL 11387094, at *6.

BACKGROUND

In this patent infringement suit brought under the Biologics Price Competition and Innovation Act, Regeneron contends that Mylan's application for FDA approval of its proposed copy or "biosimilar" of EYLEA® infringed 24 Regeneron patents. As required by the Court's Scheduling Order, Regeneron selected six patents to litigate in the initial stage of this matter and potentially bring to trial next June: one formulation patent (U.S. Patent No. 11,084,865), three manufacturing patents (U.S. Patent Nos. 11,053,280; 11,104,715; and 11,299,532), and two method-of use-patents (the '601 and '572 patents). *See* ECF 88. This narrowing will enable Regeneron to pursue its statutory right to an injunction against infringement of its patents by Mylan's biosimilar under 42 U.S.C. § 271(e)(4)(D).

Mylan asserts affirmative defenses of inequitable conduct and unclean hands as a result of alleged inequitable conduct, but provides no factual allegations in support. *See* ECF 47 at 74-75 (Nos. 60-61). At best, the defenses might be read as incorporating the inequitable conduct allegations set forth in Mylan's counterclaims seeking declarations of non-infringement and invalidity. Those allegations relate to six of the 24 patents asserted in Regeneron's Complaint, two of which are currently at issue in this stage of the litigation: the '601 and '572 patents. Those patents, Mylan contends, are unenforceable because of inequitable conduct during the

prosecution of, and *inter partes* review ("IPR")[5] proceedings concerning, the '338 and '069 patents. *See* ECF 47 at 105, 116.

In particular, Mylan asserts three types of inequitable conduct. *First*, it asserts that, in the applications for the '338 and '069 patents, Regeneron failed to disclose purported prior art: Regeneron's own press releases, Forms 10-Q and 10-K, and industry publications. *See* ECF 47 at 88-89, 92. *Second*, Mylan claims that Regeneron "made arguments to the PTO which were intentionally misleading and inaccurate" during prosecution of the '338 and '069 patents, "including statements regarding the purported 'standard of care' and the state of the art." ECF 47 at 89, 92. *Third*, Mylan contends that Regeneron made misstatements during one IPR related to the '338 patent (IPR2021-00881), one IPR related to the '069 patent (IPR2021-00880), and one post-grant review ("PGR")[6] related to U.S. Patent No. 10,857,231 (the "'231 patent") (PGR2021-00117). *See* ECF 47 at 90, 93.

On December 9, 2022, Regeneron notified Mylan that its allegations were meritless, and that Regeneron would seek judgment on the pleadings unless Mylan withdrew them. Mylan declined to do so.

[5] An IPR is an adversarial trial held before the Patent Trial and Appeal Board ("PTAB") to review the patentability of an invention after a patent is issued. 31 U.S.C. §§ 316(c), 318(a). Any person who is not the owner of a patent may file a petition to initiate an IPR. *Id.* § 311(a).

[6] A post-grant review, like an IPR, is an adversarial trial held before the PTAB to review the patentability of an invention after a patent is issued, upon petition of any person who is not the patent owner. 35 U.S.C. § 321(a), (b). The difference between an IPR and a PGR is that a PGR may be sought in a broader set of circumstances. 77 Fed. Reg. 48,684 (Aug. 14, 2012).

ARGUMENT

I. MYLAN FAILS TO PLEAD ANY OF ITS THEORIES OF INEQUITABLE CONDUCT WITH PARTICULARITY.

All of Mylan's theories concerning the '338 and '069 patents—which are not currently at issue, but, according to Mylan, infect the patents that are—fail because Mylan has not satisfied the Federal Circuit's standard for pleading inequitable conduct with particularity. Because Mylan has not sufficiently pleaded inequitable conduct in the earlier patents, it cannot allege that such conduct tainted subsequent patents. *See In re Omeprazole Patent Litig.*, 483 F.3d 1364, 1375 (Fed. Cir. 2007) (holding that, because accused infringer failed to show inequitable conduct as to earlier patent, its arguments of "infectious unenforceability" concerning later patents failed). The Court should grant judgment on the pleadings to Regeneron for this reason alone.

The Federal Circuit explained the exacting requirements for pleading inequitable conduct in *Exergen Corporation v. Wal-Mart Stores, Inc*. There, an infringement defendant sought to assert an inequitable conduct defense and counterclaim, contending the plaintiff had failed to disclose prior art in its patent application and misrepresented other information in arguments to the PTO. 575 F.3d at 1312, 1325-26. The court affirmed the district court's rejection of the proposed pleading. *See id.* at 1316. The court noted several areas in which the pleading fell short, including its failure to (1) identify an individual who deliberately withheld information from the PTO, (2) identify the claims of the patent at issue that the withheld references concerned, (3) identify where in the references the material information was located, (4) explain why the withheld references were material, (5) explain how an examiner would have used the information to assess patentability, and (6) plead facts that would give rise to a reasonable inference of scienter. *Id.* at 1329-30. Mylan's pleadings suffer from the same deficiencies.

Mylan's affirmative defenses include no factual allegations at all. Regeneron is entitled to judgment on the pleadings as to them for that reason alone. *See Cent. Admixture*, 482 F.3d at 1357 (affirming denial of leave to amend answer because proposed inequitable conduct affirmative defense was inadequately pleaded).

As for Mylan's counterclaims, all of its allegations attribute the purported inequitable conduct to "Regeneron, and/or its agents." ECF 47 at 88-90, 92-94. But pleading inequitable conduct requires identifying a specific individual associated with either a patent application or a subsequent proceeding who knew of the material information and deliberately withheld or misrepresented it. *See Exergen*, 575 F.3d at 1329 (application); *UUSI, LLC v. United States*, 133 Fed. Cl. 263, 273 (2017) (PTAB proceeding). Identifying an entity instead improperly ignores the principle that "[t]he duty of candor and good faith in dealing with the PTO applies to individuals, not organizations." *Senju Pharm. Co. v. Apotex, Inc.*, 921 F. Supp. 2d 297, 307 (D. Del. 2013) (citing *Exergen*, 575 F.3d at 1329). The court in *Correct Craft IP Holdings v. Malibu Boats* found pleadings similar to Mylan's insufficient: "[T]he pleadings again allege generally that 'Correct Craft Prosecutors' perpetrated fraud on the PTO. . . . Thus, the Amended Complaint fails to name a specific prosecutor(s) associated with the filing or prosecution of the application who both knew the material information and deliberately withheld or misrepresented it." 2010 WL 598693, at *5 (M.D. Fla. Feb. 17, 2010). The same is true here.

Similarly, Mylan "fails to identify which claims, and which limitations in those claims, the withheld references are relevant to, and where in those references the material information is found—i.e., the 'what' and 'where' of the material omissions." *Exergen*, 575 F.3d at 1329. That alone was "fatal" to the defendant's claims in *Exergen*, and likewise is fatal to Mylan's claims here. *Id*. at 1329-30.

Nor does Mylan identify where in the alleged prior art the material information was located, why it was material, or how an examiner would have used it to assess patentability. With respect to the Forms 10-K and 10-Q and "industry publications" Mylan claims were withheld, Mylan provides no detail at all. ECF 47 at 88-89, ("10-Q forms, and 10-K forms, as well as industry publications, . . . were withheld from the PTO."), 92-93 (same). Nor does Mylan specify Regeneron's alleged misstatement regarding standard of care and state of the art. *See* ECF 47 at 89 (citing "[a]pplicant [r]emarks" generally), 92 (same). As for Regeneron's statements in proceedings after the patents were issued, Mylan alleges that misleading positions were taken in three proceedings but cites only one submission specifically. *See* ECF 47 at 90 (citing Paper 41 from IPR2021-00881), 93 (same). And even then Mylan refers generally to a 12-page section of the brief without identifying the language or argument at issue. *See id*. Such vague pleading is not sufficient. *See Exergen*, 575 F.3d at 1329; *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1575 (Fed. Cir. 1997) ("What is relevant is whether [the withheld material] discloses subject matter relevant to the examination of the . . . patent application that is not taught by the [material already before the PTO]."); *Systemation, Inc. v. Engel Indus., Inc.*, 183 F.R.D. 49, 51 (D. Mass. 1998) (finding that party alleging inequitable conduct did not meet its pleading burden because it "failed to identify any particular prior art it claims should have been disclosed to the Patent and Trademark Office").

Finally, Mylan does not allege facts supporting an inference that any "specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO." *Exergen*, 575 F.3d at 1329-30. With respect to knowledge, Mylan states only that, "upon information and belief, Regeneron was aware of the misleading and inaccurate statements made

to the PTO during prosecution, and given that many of the prior art references were Regeneron's own publications, Regeneron had knowledge of the invalidating disclosures of the prior art." ECF 47 at 90, 93. Such a conclusory and general allegation, however, "provides no factual basis to infer that any *specific individual*, who owed a duty of disclosure in prosecuting the ['338 or '069] patent[s], knew of the specific information in the [undisclosed references] that is alleged to be material." *Exergen*, 575 F.3d at 1330 (emphasis added).

With respect to deceptive intent, Mylan states that "the most reasonable inference to be drawn from Regeneron's withholding of the above references from the PTO and misleading and inaccurate statements made to the PTO, is that the actions were done with the specific intent to deceive." ECF 47 at 90; *see id.* at 93. But Mylan alleges no facts to support its bald claim. Withholding—which Mylan in any event fails to allege with particularity—by itself cannot support an inference of intent. *See, e.g.*, *Am. GNC Corp. v. LG Elecs., Inc.*, 2018 WL 400346, at *7 (S.D. Cal. Jan. 12, 2018) (holding that mere failure to disclose "fail[s] to show specific intent to deceive the PTO"). Courts have accordingly found allegations like Mylan's insufficient. *See Prowess, Inc. v. RaySearch Lab'ys*, *AB*, 953 F. Supp. 2d 638, 652-53 (D. Md. 2013) (finding allegations of specific intent inadequate when defendants asserted "[w]ithout elaboration" that "the only reasonable inference" to be drawn from . . . [a plaintiff's failure to disclose references was] that the references were withheld 'with the specific intent to deceive the [PTO]' "). To the extent Mylan relies on Regeneron's submission of the purportedly undisclosed references in subsequent patent applications, the Federal Circuit has warned that "[t]he mere fact that an applicant disclosed a reference during prosecution of one application, but did not disclose it during prosecution of a related application, is insufficient to meet the threshold level of deceptive intent required to support an allegation of inequitable conduct." *Exergen*, 575 F.3d at 1331.

For all these reasons, Mylan has not adequately alleged any inequitable conduct in connection with the '338 patent or the '069 patent. *See id*. at 1330. Having failed to allege inequitable conduct in these earlier patents, Mylan's claim that they infect the '601 and '572 patents necessarily fails. *See Omeprazole*, 483 F.3d at 1375. The Court can grant this Motion in full for that reason alone without going further.

II. REGENERON CURED ANY ALLEGED NONDISCLOSURE THAT COULD HAVE INFECTED THE '601 AND '572 PATENTS.

Mylan's claims that non-disclosures in the '338 and '069 patent applications infected the '601 and '572 patents fails for a separate, independent reason: Regeneron's applications for the latter patents cured any alleged deficiency by disclosing the materials Mylan cites.[7] Mylan fails to identify any press releases, forms, or publications it contends Regeneron should have submitted in the later applications. Indeed, if any materials were missing from the later patent applications, Mylan would have asserted that absence as inequitable conduct itself, rather than invoking the earlier applications. By failing to do so Mylan has waived any claim of non-disclosures in the '601 and '572 patent applications. *See Suntrust Mortg., Inc. v. United Guar. Residential Ins. Co. of N.C.*, 508 F. App'x 243, 252 (4th Cir. 2013) (holding that defendant forfeited defense not raised in answer). Those concededly complete disclosures cure any potential inequitable conduct based on non-disclosure in the '601 and '572 applications. *See*

[7] Ex. A (Excerpt of File History of U.S. Appl. No. 16/397,267, resulting in '601 patent) at RGN-EYLEA-MYLAN-00001568-72; Ex. B (Excerpt of File History of U.S. Appl. No. 17/352,892, resulting in '572 patent) at RGN-EYLEA-MYLAN-00604647-63. Courts may "consider facts and documents subject to judicial notice without converting" a Rule 12(c) motion into a motion for summary judgment. *Clatterbuck v. City of Charlottesville*, 708 F.3d 549, 557 (4th Cir. 2013). And it is well-established that patent applications and prosecution histories are subject to judicial notice. *See, e.g.*, *Data Engine Techs. LLC v. Google LLC*, 906 F.3d 999, 1008 n.2 (Fed. Cir. 2018); *Anderson v. Kimberly-Clark Corp.*, 570 F. App'x 927, 932 n.3 (Fed. Cir. 2014); *Ubisoft Ent., S.A. v. Yousician Oy*, 401 F. Supp. 3d 644, 652 n.9 (E.D.N.C. 2019); *Classen Immunotherapies, Inc. v. Shionogi, Inc.*, 993 F. Supp. 2d 569, 580 n.10 (D. Md. 2014).

Grantley Pat. Holdings, Ltd. v. Clear Channel Commc'ns, Inc., 2008 WL 901175, at *6 (E.D. Tex. Mar. 31, 2008) ("It is difficult to imagine how any inequitable conduct with respect to the '047 patent 'infected' the four later patents when those patents explicitly incorporated the publication by reference into their specifications."); *Bos. Sci.*, 2008 WL 11387094, at *6 (holding that failure to disclose prior art in earlier applications did not infect subsequent applications in which prior art was disclosed).

III. THE ALLEGED MISREPRESENTATIONS ARE ATTORNEY ARGUMENT THAT CANNOT CONSTITUTE INEQUITABLE CONDUCT.

Mylan also claims that Regeneron misled the PTO in the prosecution of, and other proceedings concerning, the '338 and '069 patents regarding the standard of care, state of the art, and prior art. That claim too fails as a matter of law for an independent reason: the statements Mylan apparently challenges were attorney argument, which the Federal Circuit has held cannot be inequitable conduct.

Attorney arguments interpreting prior art available to the examiner cannot constitute a material misrepresentation. *See Young*, 492 F.3d at 1348. "While the law prohibits genuine misrepresentations of material fact, a prosecuting attorney is free to present argument in favor of patentability without fear of committing inequitable conduct." *Rothman v. Target Corp.*, 556 F.3d 1310, 1328-29 (Fed. Cir. 2009). This doctrine protects an applicant's "interpretation of its claims and teachings of prior art"[8] as well as the applicant's "attempts to distinguish its patent

[8] *Innogenetics, N.V. v. Abbott Lab'ys*, 512 F.3d 1363, 1379 (Fed. Cir. 2008).

from the prior art,"[9] because when an examiner is aware of prior art, he can review that art independently and "reach his own conclusion."[10]

Mylan asserts that Regeneron misled the PTO about the standard of care for treating certain eye conditions and the state of the art at the time of the '338 and '069 applications. *See* ECF 47 at 89, 92. Here, standard of care refers to the accepted treatment for the diseases aflibercept addresses. State of the art refers to existing, publicly available information at the time of a patent application. *See Yates v. Air & Liquid Sys. Corp.*, 2014 WL 4923603, at *15 (E.D.N.C. Sept. 30, 2014), *on reconsideration sub nom. Yates v. Ford Motor Co.*, 2015 WL 9222834 (E.D.N.C. Dec. 17, 2015) (citation omitted) ("State of the art represents all of the available knowledge on a subject at a given time, and this includes scientific, medical, engineering, and any other knowledge that may be available."). Mylan's counterclaims do not specify Regeneron's alleged misstatement, but Regeneron assumes Mylan takes issue with Regeneron's applicant remarks during IPR proceedings on the '338 and '069 patents that "[a]t the time of the invention the well accepted standard of care for the treatment of the neovascular (or wet) form of age-related macular degeneration [] was to administer an antibody formulation (ranibizumab) by injection to the eye once per month." Ex. C at MYL-AFL0000162; Ex. D at MYL-AFL0001695. This was Regeneron's counsel's interpretation of the prior art concerning

[9] *LifeScan, Inc. v. Home Diagnostics, Inc.*, 103 F. Supp. 2d 379, 386 (D. Del. 2000), *aff'd*, 13 F. App'x 940 (Fed. Cir. 2001) ("[T]he mere fact that a patent applicant attempts to distinguish its patent from the prior art does not constitute a material omission or misrepresentation . . . ."); *accord Young*, 492 F.3d at 1348.

[10] *Akzo N.V. v. U.S. Int'l Trade Comm'n*, 808 F.2d 1471, 1482 (Fed. Cir. 1986). *See also Beckman Instruments Inc. v. LKB Produkter, AB*, 1987 WL 125109, at *2 (D. Md. Sept. 15, 1987) ("The patent examiner was capable of independently evaluating the material," and applicant's "representations as to how to interpret that material cannot be the basis for a finding of inequitable conduct.").

the accepted treatment regimen for age-related macular degeneration and was based on art provided to the examiner.[11]

Similarly, Mylan asserts generally that Regeneron made misstatements during one IPR related to the '338 patent (IPR2021-00881), one IPR related to the '069 patent (IPR2021-00880), and one PGR related to the '231 patent (PGR2021-00117). *See* ECF 47 at 90, 93.[12] But Mylan cites only a 12-page section of a brief that was filed in IPR2021-00881. *See* ECF 47 at 90, 93. That section, like the applicant remarks discussed above, constitutes attorney argument that cannot form the predicate of an inequitable conduct claim. It merely summarizes prior art, such as reports regarding differences in protein molecular weights and descriptions of dosing regimens. *See* Ex. B at RGN-EYLEA-MYLAN-00605193-204.

In all of these instances, the examiner was "free to accept or reject" Regeneron's interpretations of its claims and prior art, so such interpretations cannot be material. *Innogenetics*, 512 F.3d at 1379; *see also Rothman*, 556 F.3d at 1328-29; *Young*, 492 F.3d at 1348. Even if Mylan had alleged these purported instances of inequitable conduct with particularity—which it did not—its allegations would still fail because Mylan invokes only attorney argument. And because Mylan has not alleged inequitable conduct in connection with the '338 and '069 patents, it necessarily has not alleged that such conduct infected the '601 and '572 patents. *See Omeprazole*, 483 F.3d at 1375.

---

[11] Numerous prior art references confirm the standard of care was as described. *E.g.*, Ex. A at RGN-EYLEA-MYLAN-00002258 ("Ranibizumab . . . is the only widely used drug that is currently approved by the FDA for the treatment of neovascular AMD . . . . Several ranibizumab Phase III clinical trials that have studied different treatment schedules, doses, and populations have obtained good results with monthly injections . . . ."); *see id.* at RGN-EYLEA-MYLAN-00002089, RGN-EYLEA-MYLAN-00002214, RGN-EYLEA-MYLAN-00002247.

[12] The '231 patent, the subject of PGR2021-00117, is an unrelated formulation patent—not a method-of-use patent—with separate inventors from the patents at issue here.

CONCLUSION

For the reasons set forth above, Regeneron respectfully requests that the Court enter judgment on the pleadings in Regeneron's favor as to Mylan's inequitable conduct defenses (Nos. 60-61) and counterclaims (Counts 12 and 21) regarding the '601 and '572 patents.

Date: December 16, 2022

Respectfully submitted,

Of Counsel:

David I. Berl (admitted *PHV*)
Ellen E. Oberwetter (admitted *PHV*)
Thomas S. Fletcher (admitted *PHV*)
Andrew V. Trask (admitted *PHV*)
Teagan James Gregory (admitted *PHV*)
Shaun P. Mahaffy (admitted *PHV*)
Kathryn S. Kayali (admitted *PHV*)
Arthur J. Argall III (admitted *PHV*)
Adam Pan (admitted *PHV*)
Nicholas Jordan (admitted *PHV*)
WILLIAMS & CONNOLLY LLP
680 Maine Avenue, SW
Washington, DC 20024
(202) 434-5000
dberl@wc.com
eoberwetter@wc.com
tfletcher@wc.com
atrask@wc.com
tgregory@wc.com
smahaffy@wc.com
kkayali@wc.com
aargall@wc.com
apan@wc.com
njordan@wc.com

CAREY DOUGLAS KESSLER & RUBY PLLC

/s/ Steven R. Ruby
Steven R. Ruby (WVSB No. 10752)
David R. Pogue (WVSB No. 10806)
707 Virginia Street East
901 Chase Tower (25301)
P.O. Box 913
Charleston, West Virginia 25323
(304) 345-1234
sruby@cdkrlaw.com
drpogue@cdkrlaw.com

Andrew E. Goldsmith (admitted *PHV*)
Evan T. Leo (admitted *PHV*)
Jacob E. Hartman (admitted *PHV*)
Mary Charlotte Y. Carroll (admitted *PHV*)
Sven E. Henningson (admitted *PHV*)
KELLOGG, HANSEN, TODD, FIGEL &
FREDERICK, P.L.L.C.
1615 M Street, NW, Suite 400
Washington, DC 20036
TEL: (202) 326-7900
agoldsmith@kellogghansen.com
eleo@kellogghansen.com
jhartman@kellogghansen.com
mcarroll@kellogghansen.com
shenningson@kellogghansen.com

Counsel for Plaintiff Regeneron Pharmaceuticals, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on December 16, 2022, I electronically filed the foregoing with the Clerk of the Court by using the Court's CM/ECF system. Counsel of record for all parties will be served by the Court's CM/ECF system.

/s/ Steven R. Ruby
Steven R. Ruby